REMARKS

Claims 1-3 and 8-10 are pending in the present application.

Claims 1-3 have been amended, and claims 4-7 previously cancelled, for the sole reason of advancing prosecution. Applicants, by amending or cancelling any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Claim 1 has been amended to recite a "patch comprising a backing layer and an adhesive layer disposed on the backing layer and compounded with an adhesive agent and oxybutynin and/or a pharmaceutically acceptable salt thereof, the adhesive layer comprising 1-5% by weight of a 2-ethylhexyl acrylate-vinyl acetate copolymer based on the total weight of the adhesive agent, the 2-ethylhexyl acrylate-vinyl acetate copolymer being substantially free of both carboxyl groups and hydroxyl groups in the molecule; and 10-25% by weight of a styrene-isoprene-styrene block copolymer based on the total weight of the adhesive agent, wherein the weight ratio of the 2-ethylhexyl acrylate-vinyl acetate copolymer to the styrene-isoprene-styrene block copolymer is from 1:4 to 1:19." Support for the amendment to claim 1 can be found throughout the specification and claims as originally filed. For example, please *see* the specification at page 12, line 23 to page 13, line 7.

Claim 2 has been amended to recite the "patch according to claim 1, wherein the adhesive layer comprises 10-60% by weight of an alicyclic saturated hydrocarbon resin-

based tackifier, based on the total weight of the compounds contained in the adhesive layer." Support for the amendment to claim 2 can be found throughout the specification and claims as originally filed.

Claim 3 has been amended to recite the "patch according to claim 2, wherein weight ratio of the 2-ethylhexyl acrylate-vinyl acetate copolymer to the tackifier is from 1:1 to 1:3." Support for the amendment to claim 3 can be found throughout the specification and claims as originally filed.

No new matter has been added.

In view of the remarks set forth herein, further and favorable consideration is respectfully requested.

I. At page 3 of the Official Action, claims 1-3 and 8-10 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Chono et al. (EP 1 201 232).

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to optimize the formation of the adhesive layer and sufficient skin permeability of the drug.

In view of the foregoing, Applicants respectfully traverse the rejection of claims 1-3 and 8-10.

To establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U. S. 398 (2007), "a court must ask whether the improvement is

more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

A proper case of obviousness under 35 U.S.C. §103, requires that the prior art, as a whole, must suggest the desirability of making the claimed combination and provide a reasonable expectation of success. *See In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988).

The *Dow* court further held that "In determining whether such a suggestion can fairly be gleaned from the prior art, the full field of the invention must be considered for

the person of ordinary skill is charged with knowledge of the entire body of technological literature, including that which might lead away from the claimed invention." The court in *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994), held that "A prior art reference may be said to *teach away* when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." The court in *Busch & Lamb, Inc. v. Barnes-Hind/Hydro curve, Inc.*, 796 F.2d 443 (Fed. Cir. 1986), held that "A reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered."

Regarding *teaching away*, **MPEP 2141.02** states that prior art must be considered in its entirety, including disclosures that *teach away* from the claims. See also **MPEP 2145(X)(D)**.

Secondary considerations, such as unexpected or superior results, are also sufficient to overcome a *prima facie* case of obviousness. See **MPEP 716.02 and 2145.**

It is submitted that a proper case of *prima facie* obviousness has not been established because Chono et al. do not teach or suggest every element of the presently pending claims as required by *In re Wilson*. Additionally, Applicants submit that Chono et al. teach away from the presently claimed subject matter. Further, Applicants submit that, assuming *arguendo*, a *prima facie* case was established it could not be maintained because the presently claimed subject matter exhibits unexpectedly superior properties.

Independent claim 1 is directed to patch comprising a backing layer and an adhesive layer disposed on the backing layer and compounded with an adhesive agent and oxybutynin and/or a pharmaceutically acceptable salt thereof, the adhesive layer comprising ***1-5% by weight of a 2-ethylhexyl acrylate-vinyl acetate copolymer based on the total weight of the adhesive agent***, the 2-ethylhexyl acrylate-vinyl acetate copolymer being substantially free of both carboxyl groups and hydroxyl groups in the molecule; and 10-25% by weight of a styrene-isoprene-styrene block copolymer based on the total weight of the adhesive agent, wherein the weight ratio of the 2-ethylhexyl acrylate-vinyl acetate copolymer to the styrene-isoprene-styrene block copolymer is from 1:4 to 1:19. (Emphasis added). Claims 3 and 8-10 depend, either directly or indirectly from claim 1.

In contrast, Chono et al. is directed a patch formulation comprising a basic drug, an adhesive layer, and a backing layer for supporting the adhesive layer. At paragraph 31, Chono et al. describes an acrylic polymer present in an amount of 10-98%. However, unlike the present subject matter, Chono et al. do not teach or suggest ***1-5% by weight of a 2-ethylhexyl acrylate-vinyl acetate copolymer based on the total weight of the adhesive agent***, as presently claimed. Therefore, Chono et al. do not teach or suggest every element of the presently claimed subject matter.

As described at page 13, lines 3-19, of the present specification, an amount of either acrylic or rubber polymer lower than the lowest claimed limit tends to decrease skin permeability and an amount higher than the highest claimed limit tends to decrease cohesion force of the adhesive layer. Applicants note that as Chono et fall outside of

the claimed limits, reading Chono et al. a skilled artisan would be lead in a path divergent from that taken by the Applicants in the present claims. Accordingly, Applicants submit that Chono et al. teach away from the presently claimed subject matter.

Further, as discussed, secondary considerations, such as unexpected results, are sufficient to overcome a *prima facie* case of obviousness. See **MPEP 716.02 and 2145.** Accordingly, Applicants again bring the Examiner's attention to the unexpectedly superior properties achieved by the presently claimed patch, as outlined in Tables 1 and 2, on pages 27 and 29, of the present specification.

Applicants submit that the data shows enhanced maximum skin permeation rates for the drug oxybutynin in those patch formulations that contain all the components as recited in the presently pending claims as compared to prior art patch formulations that do not include all of the presently claimed components. In particular, Examples 1-5, summarized in Tables 1 and 2, show drug permeation rates per unit area of skin achieved by the presently claimed patch. Comparative Examples 1-5, in Tables 1 and 2, show drug permeation rates for patch formulations lacking at least one of the components of the presently claimed patch. The data clearly shows that superior skin permeation rates and physical patch properties were achieved by the presently claimed patch, as compared to the drug permeation rates achieved by patch formulations lacking at least one of the presently claimed components.

Further, there is no teaching anywhere in the Chono *et al.* reference that would motivate a person of ordinary skill in the art to arrive at the particular combination of

components recited in the presently pending claims. In particular, Examples 2 and 3 in *Chono et al.* show compositions comprising oxybutynin and a blend of rubber polymers; but lacking the presently claimed copolymer. Examples 2 and 3 shown in Chono et al. reference are analogous to Comparative Examples 1, 4 and 5 shown in the present specification because the compositions disclosed in both sets of examples lack the presently claimed acrylic polymers. The data reported in Inventive Examples 1-5 of the present specification show the unexpectedly superior permeation rates achieved by the presently claimed patch as compared to the permeation rates achieved by compositions lacking an acrylic polymer.

Accordingly, the data, outlined in Tables 1 and 2, on pages 27 and 29 of the present specification, establish the unexpectedly superior results achieved by the presently claimed patch. As such, the presently pending claims are not obvious in view of Chono et al.

In view of the foregoing, Applicants submit that nothing in Chono et al. renders the subject matter of present claims 1-3 and 8-10 obvious, within the meaning of 35 USC § 103. Thus, the Examiner is respectfully requested to reconsider and withdraw this rejection of claims 1-3 and 8-10.

II. At 5 of the Official Action, claims 1, 3 and 8-9 have been provisionally rejected under the non-statutory patenting over claims 1, 3, 6, 8, 9-11 and 13-14 of co-pending U.S. Patent Application No. 10/469,612 (Tateishi et al.).

The Examiner asserts that the claims are not patentably distinct from claims 1, 3, 6, 8, 9-11 and 13-14 of co-pending U.S. Patent Application No. 10/469,612.

Applicants respectfully submit that this rejection has been obviated in view of the amendments herein. Specifically, Applicants note that as amended, the pending claims and the claims of the '612 application differ, at least, because of the recitation of a specific weight ratio of acrylic polymer to styrene polymer, as well as the recitation of the contents of the acrylic and styrene polymers. Accordingly, Applicants request that the Examiner reconsider and withdraw this rejection.

III. At page 3 of the Official Action, claims 1-3 and 8-10 have been rejected under 35 USC § 103(a) as being unpatentable over Mantelle et al. (US Patent No. 6,210,705) in view of Sablotsky (US Patent No. 4,994,267) and in further view Gale (US Patent No. 5,614,211).

The Examiner asserts that Mantelle et al. disclose a topical composition of a drug comprising an adhesive layer laid on a support containing an adhesive base and a drug and an acrylate-vinylacetate copolymer. Further, the Examiner asserts that Mantelle et al. do not disclose a styrene polymer nor a formulation comprising an acrylic polymer and a rubber polymer. Accordingly, the Examiner refers to Sablotsky, asserting that Sablotsky discloses a dermal composition comprising a drug, an acrylate polymer, a rubber polymer and a tackifying agent. Additionally, the Examiner asserts that Sablotsky discloses that styrene-isoprene-styrene block copolymers may be used in the composition. Lastly, because neither Mantelle et al. nor Sablotsky teach the use of

oxybutynin, the Examiner cites Gale which discloses the use of oxybutynin. Thus, the Examiner concludes that it would have been obvious to incorporate oxybutynin into a transdermal device as disclosed in Mantelle et al. and Sablotsky to arrive at the presently claimed subject matter.

In view of the foregoing, Applicants respectfully traverse the rejection of claims 1-3 and 8-10.

To establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U. S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was

made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

It is submitted that a proper case of *prima facie* obviousness has not been established because, whether taken alone or in combination, none of the cited references teach or suggest each and every element of the presently pending claims as required by *In re Wilson*.

Independent claim 1 is directed to patch comprising a backing layer and an adhesive layer disposed on the backing layer and compounded with an adhesive agent and oxybutynin and/or a pharmaceutically acceptable salt thereof, the adhesive layer comprising ***1-5% by weight of a 2-ethylhexyl acrylate-vinyl acetate copolymer based on the total weight of the adhesive agent***, the 2-ethylhexyl acrylate-vinyl acetate copolymer being substantially free of both carboxyl groups and hydroxyl groups in the molecule; and ***10-25% by weight of a styrene-isoprene-styrene block copolymer based on the total weight of the adhesive agent***, wherein the weight ratio of the 2-ethylhexyl acrylate-vinyl acetate copolymer to the styrene-isoprene-styrene block copolymer is from 1:4 to 1:19. (Emphasis added). Claims 3 and 8-10 depend, either directly or indirectly from claim 1.

Mantelle et al. is directed to a method of treating Attention Deficit Disorder (ADD) and Attention Deficit/Hyperactivity Disorder (ADHD) and compositions for topical application of methylphenidate comprising methylphenidate in a flexible, finite system. *See* Mantelle et al. at the abstract.

Sablotsky is directed to a dermal composition comprising a drug, a multipolymer of ethylene-vinyl acetate, an acrylic polymer, and optionally one or more monomers, a natural or synthetic rubber and a tackifying agent. *See* Sablotsky at the abstract.

Gale is directed to a device for the transdermal administration of oxybutynin comprising a microporous tie layer located between the oxybutynin reservoir and the contact adhesive. *See* Gale at the abstract.

However, unlike the presently claimed subject matter, whether taken alone or in combination, none of the cited references teach or suggest the combination of 1-5% by weight of a 2-ethylhexyl acrylate-vinyl acetate copolymer based on the total weight of the adhesive agent, the 2-ethylhexyl acrylate-vinyl acetate copolymer being substantially free of both carboxyl groups and hydroxyl groups in the molecule...and 10-25% by weight of a styrene-isoprene-styrene block copolymer based on the total weight of the adhesive agent, as presently claimed. Accordingly, the cited references do not teach or suggest each and every element of the presently claimed subject matter.

In addition, Applicants respectfully submit that, as set forth in section I. above, the presently claimed subject matter exhibits unexpectedly superior results in comparison the cited art. The discussion in section I. is hereby incorporated by reference. For a complete discussion, please *see* section I. above.

In view of the foregoing, Applicants submit that nothing in any of the cited references, whether taken alone or in combination, renders the subject matter of present claims 1-3 and 8-10 obvious, within the meaning of 35 USC § 103. Thus, the Examiner is respectfully requested to reconsider and withdraw this rejection of claims 1-3 and 8-10.

CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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